XII. Summary of Safety and Effectiveness

Date of Preparation:	September 20, 2004
Device Name:	i-Promotions Contact Lens Case
Classification Name:	Contact Lens Case
Manufacturer:	i-Promotions, Inc. 9522 Gravois Rd. St. Louis, MO 63123
Contact:	Charlotte Slankard President i-Promotion, Inc.
Predicate Device:	Pelican Contact Lens Case K030987 And OptiLens™ Contact Lens Case K920064
Device Description And Intended Use:	The i-Promotions Contact Lens Case consists of a lens case base with adjoining dual wells for the containment of fluid, and separate integral hinged self-sealing caps. The i-Promotions Contact Lens Case is intended for storage during disinfection of soft, rigid gas permeable or hard contact lenses. Not to be used with heat disinfection. Use only with chemical disinfection.
Summary of Safety Testing:	NAMSA preformed cytotoxicity testing on six completed i-Promotions Contact Lens Cases. The six cases tested were created using the correct proportion of Dow Chemical Company Low Density Polyethylene Product #9931 and one of five Carolina Color Corporation (listed on page 15). One case was created using no colorant. Five cases were created using one of each colorant. NAMSA took an equal sampling from each of the six cases and combined the sampling to perform one cytotoxicity test. The six completed contact lens cases were tested using the biological and toxicology tests recommended by the USPXXII and the results of these studies show that the product is safe for its intended use.

Table I
Summary of Equivalences and Differences
510(k) Device and Predicate Devices
(Amended 1-14-05)

Device Name	510(k) i-Promotions Contact Lens Case	Pelican Contact Lens Storage Case (K030987) Item #600	Opti-Lens™ Contact Lens Case (K920064)
Indications	Storage and Disinfection of Soft, Rigid Gas Permeable or Hard Lenses	Storage and Disinfection of Soft, Rigid Gas Permeable or Hard Lenses	Storage and Disinfection of Soft, Rigid Gas Permeable or Hard Lenses
Disinfection Type	Chemical (Not Heat)	Chemical (Not Heat)	Chemical (Not Heat)
Design	Two Adjoining Wells With Integral Hinged Caps Into Which Respective Lenses are Immersed	Two Adjoining Wells With Integral Hinged Caps Into Which Respective Lenses are Immersed	Two Adjoining Wells With Screw Top Caps Into Which Respective Lenses are Immersed
Materials	-Dow Chemical Company Low Density Polyethylene Dow Product #9931 -One of the Carolina Color Corporation Colorants listed in List of Materials Page15	-Dow Chemical Company Low Density Polyethylene Dow Product #9931 See 510(k) (K030987) Item #600	-M.A. Industries, Inc. #POO11AL Polypropylene
Labeling	Refers to product as i-Promotions contact lens case; instructs patient to clean lens case with a disinfecting solution recommended for this purpose	See 510(k) (K030987) Item #600	Refers to product as Opti-Lens contact lens case; instructs patient to clean lens case with Opti-Free Daily Cleaner

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2005

i-Promotions, Inc.
c/o Ms. Charlotte Slankard
9522 Gravois Rd.
St. Louis, MO 63123

Re: K042578
Trade/Device Name: i-Promotion Contact Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Contact Lens Storage Case
Regulatory Class: Class II
Product Code: LRX
Dated: December 27, 2004
Received: December 30, 2004

Dear Ms. Slankard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number: K042578

Device Name: i-Promotions Contact Lens Case

Indications for Use:

For storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses.

For use during chemical disinfection only. Not to be used with heat.

Over the Counter Use
(21 CFR 801 Subpart C)

Over-the-Counter Use ✓

Patrick Lee Cohen, MD

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number 042578